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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/396,710	09/15/1999	AVI J. ASHKENAZI	P1101P2	7837

7590 04/29/2004

DIANE L MARSCHANG
GENENTECH INC
1 DNA WAY
SOUTH SAN FRANCISCO, CA 940804990

EXAMINER

KAUFMAN, CLAIRE M

ART UNIT PAPER NUMBER

1646

DATE MAILED: 04/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action

Application No.

09/396,710

Applicant(s)

ASHKENAZI ET AL.

Examiner

Claire M. Kaufman

Art Unit

1646

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED April 15, 2004, FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
- ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on 15 April 2004. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see Note below);
- (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____

3. ☒ Applicant's reply has overcome the following rejection(s): rejection of claims 32-47 under 35 USC 112, 1st paragraph.
4. ☒ Newly proposed or amended claim(s) 32-47 would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: see attached.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: 14-47.

Claim(s) objected to: _____

Claim(s) rejected: 1-5, 10-13.

Claim(s) withdrawn from consideration: _____

8. ☐ The drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☒ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). 1/20/04, 4/15/04.
10. ☐ Other: _____

Advisory Action Continuation Sheet

Paper 0404

Inventorship

In view of the papers filed April 15, 2004, the inventorship in this nonprovisional application has been changed by the deletion of Inventors A. Chuntharapai and K. J. Kim.

The Office of Initial Patent Examination (OIPE) will be informed for issuance of a corrected filing receipt and PTO PALM data to reflect the inventorship as corrected.

Continuation of #5:

Applicants argue that it would not require undue experimentation to determine if an agonist antibody binds an Apo-2 receptor and induces apoptosis and if the receptor has at least 80% identity to SEQ ID NO:1. The argument has been fully considered, but is not persuasive. It is noted that the feature upon which Applicants rely (*i.e.*, that the Apo-2 receptor have the ability to induce apoptosis) is not recited in the definition of Apo-2 receptor in the specification. So while the skilled artisan may be able to test whether an antibody can bind a polypeptide 80% identical and can subsequently induce apoptosis upon binding/activation by a ligand or agonistic antibody, the “Apo-2” receptor defined in the specification has no such limitation. That is why the term “Apo-2” used alone without (further) limitation of structure and/or function in the claims makes the claims not enabled. It would have been unpredictable at the time the invention was filed which polypeptides showing at least 80% identity to SEQ ID NO:1 were capable of causing apoptosis upon activation by binding and, therefore, which antibodies to a broadly defined “Apo-2” polypeptide would function in the claimed methods.

Applicants argue that “one skilled in the art could readily distinguish an Apo-2 polypeptide falling within the scope of [the] claims ... from other members of the TNF receptor family.” The argument has been fully considered, but is not persuasive. One skilled in the art could only distinguish an “Apo-2” polypeptide within the scope of the claims so far as a polypeptide at least 80% identical to SEQ ID NO:1 might be within the scope. Because of the lack of specific functional limitation of an “Apo-2” polypeptide, one could not without further information or undue experimentation distinguish the subgroup of polypeptides falling within the

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broad structural limitation of an "Apo-2" polypeptide for which an agonistic antibody to the polypeptide could be made that, upon binding to the polypeptide, leads to apoptosis.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Claire M. Kaufman, whose telephone number is (571)272-0873. Dr. Kaufman can generally be reached Monday, Tuesday and Thursday from 8:30AM to 2:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached at (571)272-0871.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196.


Official papers filed by fax should be directed to (703) 872-9306. NOTE: If applicant *does* submit a paper by fax, the original signed copy should be retained by the applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Claire M. Kaufman, Ph.D.



Patent Examiner, Art Unit 1646

April 28, 2004



YVONNE EYLER, Ph.D.
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600